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REMARKS

A fresh Power of Attorney to the undersigned firm is being filed along with this document, and it is requested that the address for correspondence be accordingly changed.

It is submitted that claim 33 as amended would not be anticipated by the disclosure of the U.S. Patent No. 5,476,510 to Eberhardt et al. Eberhardt et al. disclose a holder for placing a tissue valve in a position in the aorta. As best seen in FIGS. 13 and 14, the tissue valve 36 has a three commissure posts 38 spaced apart from each other at approximately 120°, each post defines the juncture between adjacent flexible leaflets. The two general types of prosthetic heart valves are described in the paragraph at Column 1, lines 14-29. Applicant's invention is directed not to a bioprosthetic valve with which Eberhardt et al. are concerned, but instead to the first class of valves there described, which are generally referred to in the art as "mechanical" valves and which have a relatively rigid, tubular valve body. The bioprosthetic valve illustrated in Eberhardt et al. (along with the holder which is being claimed) is not a substantially rigid tubular structure; moreover, it merely contains the traditional sewing ring 42 which surrounds the circular base in the immediate region of the valve inlet. A conventional sewing ring is continuous and flexible, usually being made of rolls of fabric through which the valve is sutured into place.

With respect to amended claim 33, there is not shown a mechanical valve having a substantially rigid tubular valve body about which an external discontinuous semi-rigid sewing flange is circumferentially disposed having portions spaced radially from said surface, in combination with a sealing ring which is spaced longitudinally both from said inlet and from said sewing flange and which sealing ring comprises a continuous circumferential nonfiborous tissue adherence band. In view of the differences now distinctly recited, it is submitted that the rejection under 35 U.S.C. 102 should be reconsidered and withdrawn and that claim 33 and dependent claim 34

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should be allowed.

Amended claim 1 defines a heart valve that would not be obvious from the disclosure of U.S. Patent No. 5,037,434 to Lane in view of U.S. Patent No. 5,908,451 to Yeo. Although Yeo does disclose a mechanical heart valve, Lane discloses a bioprosthetic heart valve (as stated in the abstract on the title page of Lane). The inner frame of Lane that supports the three commissures is elastic, permitting the commissures to bend in toward the center of the prosthetic valve. These three elastic commissures are in no way the equivalent of Applicant's recited tubular valve body. Moreover, bioprosthetic valves like Lane and mechanical heart valves like Yeo are like apples and oranges; both operate by totally different mechanisms and have completely dissimilar structures. There is clearly no teaching in the Lane patent that would suggest changes to the valve structure shown in Yeo, which admittedly shows a tubular valve body having a flared inlet end; however, it is there that all similarity ends. The Yeo patent is unconcerned with how it would be mounted in a patient; it is simply pointed out, at column 4, lines 20-28, that the exterior surface might simply be provided with a groove to facilitate the attachment of a standard circumferential sewing ring.

Amended claim 1 recites a semirigid sewing flange, which is spaced from the flared inlet end by a groove and further defines this semirigid sewing flange as comprising at least first and second flange portions which are spaced circumferentially apart from each other and longitudinally from the flared inlet end. It is further recited that the flange portions comprise at least one post for securing sutures (see for example post 31 in FIG. 1), which posts are spaced radially from the outer surface to permit the passage of sutures therebetween. It is submitted that it should be clear that the structure now claimed is far afield from the standard bioprosthetic valve shown in Lane which merely employs a traditional suture ring 18. The groove 46 to which the Examiner makes reference in the Lane patent (see FIG. 9) is in the exterior surface of the annular base 42 of the support ring which supports the free upstanding elastic

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commissures shown in FIG. 2. The groove provides a location to mount the "conventional sewing cuff 116 with silicone rubber insert" (Col. 7, lines 54-56). Upon reflection, it is believed the Examiner will see that there is little similarity between the conventional, flexible, fabric sewing rings talked about in these three patents and the arrangement claimed in amended claim 1. Accordingly, it is submitted that the rejection of claim 1 under 35 U.S.C. 103 should be reconsidered and withdrawn, and that claim 1 and dependent claims 2-7 should be allowed.

Although, claims 9-16 have been nominally withdrawn, claim 9 has been amended in a manner similar to the amendments that were made to claim 1. It is submitted that claim 1 (and new claim 41) would be generic to claim 9, and inasmuch as the specific edge structure of the cleat shown in FIG. 6, which utilizes side notches 63, is not being relied upon for patentability over the cited prior art, it is submitted that these claims should be allowed along with claims 1-7 for the same reasons.

The remaining non-elected claims 17 to 32 have been canceled. The Examiner's indication that claim 8 contains allowable subject matter is acknowledged, and claim 8 has been canceled and incorporated as a part of a new claim 35 which is here presented along with dependent claims 36-40, which dependant claims find response in original claims 2-7.

New claim 41 defines Applicant's aortic mechanical valve (which has a substantially rigid tubular body and flow control means for reversibly sealing across the interior surface to establish substantially unidirectional flow) as having a circumferential continuous tissue adherence band which circumscribes the outer surface of the body and which is located between and spaced from the inlet end of the tubular valve body and the flange which is used to attach the valve body in the aorta of the patient by sutures which extend through the patient's tissue.

The prior art patents cited fail to disclose such a mounting configuration for the substantially rigid body of a mechanical valve. Such valves are traditionally mounted,

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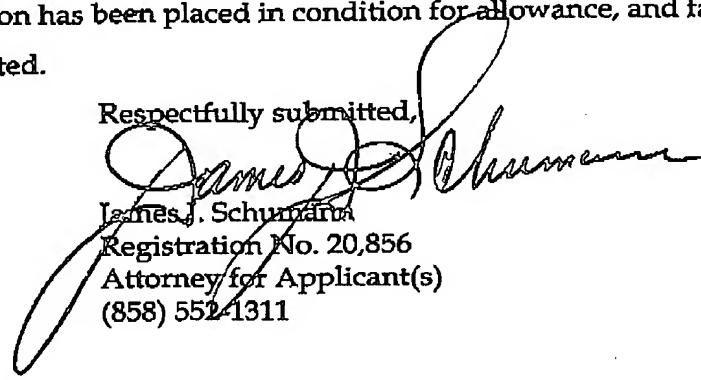
as shown in U.S. Patent No. 5,772,694 to Bokros et al. (supplied as part of the IDS), by simply employing a sewing ring 81 which is located for example by a thickened band 29a on the exterior surface which it surrounds. The concept of using a continuous tissue adherence band which circumscribes the outer surface of the valve body at a location between and spaced apart from the inlet end of the valve body and the attachment flange (which extends radially outward from the outer surface and is employed to suture the valve to the patient's tissue) is totally foreign to such commercial mechanical heart valves.

Dependent claim 42 further defines the dissimilarity between Applicant's structure and anything shown in the prior art by reciting that the flange includes at least first and second flange portions which are spaced circumferentially apart from each other (being formed with openings or notches for securing sutures) and which extend obliquely from the outer valve body surface and in a downstream direction, as clearly shown in FIGS. 1, 1A, 1B and 2. FIG. 2 shows that the sutures pass between the radially inner surface of the post of these flange portions and the outer surface of the valve body. New claims 43-47 find support in original claims 2-7. New claim 48 defines the semirigid flange portions as being formed integral with the valve body, as shown in FIG. 1 and as described on page 15, lines 20-25 of the specification. New claim 49 defines the arrangement illustrated in FIG. 1 where the tissue adherence band 24 is located generally centrally within the groove 20 which extends to the outwardly flared inlet end of the valve body. For the reasons set forth previously with respect to the three prior art patents applied by the Examiner, and for the further distinctions mentioned above, it is believed that new claims 41-49 should be allowed, and allowance thereof is respectfully requested.

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In view of the foregoing amendments and remarks, it is believed that claims 1-7 and 33-49 should be allowed. Moreover, it is requested that presently withdrawn claims 9-16 considered and also allowed. In the absence of more pertinent prior art, it is believed that this application has been placed in condition for allowance, and favorable action is courteously solicited.

Respectfully submitted,


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